

Infection Prevention: A History of Change

P A P E R # 4 • J U N E 1 9 9 6

**Prepared By: Noel McIntosh, MD, ScD
President**

**Linda Tietjen, MPH
Infection Prevention Consultant**

JHPIEGO Strategy Papers are designed to summarize JHPIEGO's experience in reproductive health, with a focus on education and training. The papers are intended for use by program staff of JHPIEGO, USAID and its cooperating agencies and other organizations providing or receiving technical assistance in the area of reproductive health training.

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JHPIEGO, an affiliate of the Johns Hopkins University, is a nonprofit organization dedicated to improving the health of women and families globally.

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Background

The idea of collecting simple, inexpensive infection prevention (IP) practices being used around the world and organizing them in a manual began in the early 1980s in Nepal. The first published document incorporating many of these practices, *A Manual on Infection Control in Health Care Facilities*, was published in 1984. Although this manual dealt primarily with sanitation and waste disposal issues in hospitals, it served to highlight the importance of practical preventive measures for reducing the risk of disease transmission, especially in countries where resources are limited.

This paperback manual was produced by His Majesty's Government of Nepal through support from the Dooley Foundation/INTERMED and the World Health Organization (WHO). It was originally written in Nepali by Ms. Rukmini Charnan Shrestha, Chief of the Division of Nursing and members of her staff with assistance from Wendy Cronin and Linda Tietjen. Subsequently, it was translated into English and published by the South East Asia Regional Office of WHO (SEARO Regional Health Papers No. 18) in 1988.

Other than the SEARO manual, no complete set of infection prevention guidelines existed for use in countries with significant resource constraints. Furthermore, much of the available information being disseminated by international health organizations at that time was inconsistent and often inaccurate. Thus, it was obvious that a comprehensive set of IP guidelines was needed if any progress was to be made in this important aspect of reproductive health service delivery.

Infection Prevention Manual

By 1989 sufficient new IP information and more practical, field-driven solutions had become available (Tietjen and McIntosh 1989). Therefore, in the summer of 1990, with assistance from the USAID/Kenya mission, the first draft of JHPIEGO's IP reference manual was completed and systematic field-testing of the most promising IP processes and practices began. Over the next 10 months the draft manual was revised extensively based on results of the field testing and input from many users and external reviewers.

As progress in evaluating and organizing the new information occurred, it became increasingly obvious that little progress could be made unless the recommended IP practices were universally accepted. Unfortunately, the concept of **infection control**, with its focus on decreasing postoperative and nosocomial (primarily hospital-acquired) infections, still dominated medical practitioners' thinking. The concept of **infection prevention**, which emphasizes both client/patient and service provider safety as quality of care issues, was just emerging. Thus, universal acceptance of a uniform set of IP practices and processes seemed remote at best. To better understand this situation, it is necessary to turn the clock back a few years.

Key Constraints

Deaths following female voluntary sterilization procedures (minilaparotomy and laparoscopy) performed in developing countries substantially decreased by the mid-1980s (from 7.1 to 3.7 per 100,000 procedures) (Khairullah, Huber and Gonzalez 1992). Although infections still remained a leading cause of morbidity and mortality, there was

limited funding to support solutions that could further reduce infection-related complications. Key constraints at that time were:

- A persistent misconception that expensive, high-tech equipment and facilities were needed to provide a safer environment to perform surgery.
- A mistaken belief that autoclaving (pressurized steam) will sterilize instruments and other items regardless of whether or not they have been decontaminated and thoroughly cleaned.
- A failure to appreciate the importance of simple IP practices, such as handwashing and use of barriers (protective gloves), to reduce the risk of transmitting serious diseases to clients and health care workers.

Emergence of the AIDS Epidemic

By the late 1980s, there was increasing awareness and recognition by international public health leaders of the need to develop and implement preventive practices which would make provision of reproductive health services, especially clinical procedures such as minilaparotomy, safer for both clients and staff. In fact, it was not until the global emergence of the AIDS epidemic that the appropriateness of a two-fold approach—aimed at preventing postoperative infections as well as minimizing the risk of serious disease transmission for both clients and staff—began to be accepted.

Need for Comprehensive Infection Prevention Guidelines

The **primary purpose** of the IP manual was to enable health care professionals and managers to develop uniform policies and practices for use in any

type or size service delivery facility, regardless of its location. In addition, the manual was specifically designed to supply the essential IP information in a simple, easily understandable format so that users could find what they want, when they needed it.

Infection prevention in family planning and health care facilities, whether free-standing clinics or mobile centers, has two **primary objectives**:

1. To prevent major postoperative infections when providing surgical contraceptive methods (IUDs or voluntary sterilization) or performing other invasive procedures.
2. To minimize the risk of transmitting serious infections such as hepatitis B and AIDS not only to clients but also to service providers and staff, including cleaning and housekeeping personnel.

The IP **principles** on which the manual is based are:

- Consider every person (client or staff) infectious.
- Wash hands—the most practical procedure for preventing cross-contamination (person to person).
- Wear gloves before touching anything wet—broken skin, mucous membranes, blood or other body fluids (secretions or excretions)—or soiled instruments and other items.
- Use physical barriers (protective goggles, face masks and aprons) if splashes and spills of any body fluids (secretions or excretions) are anticipated.
- Use safe work practices, such as not recapping or bending needles, safely passing sharp instruments and properly disposing of medical waste.

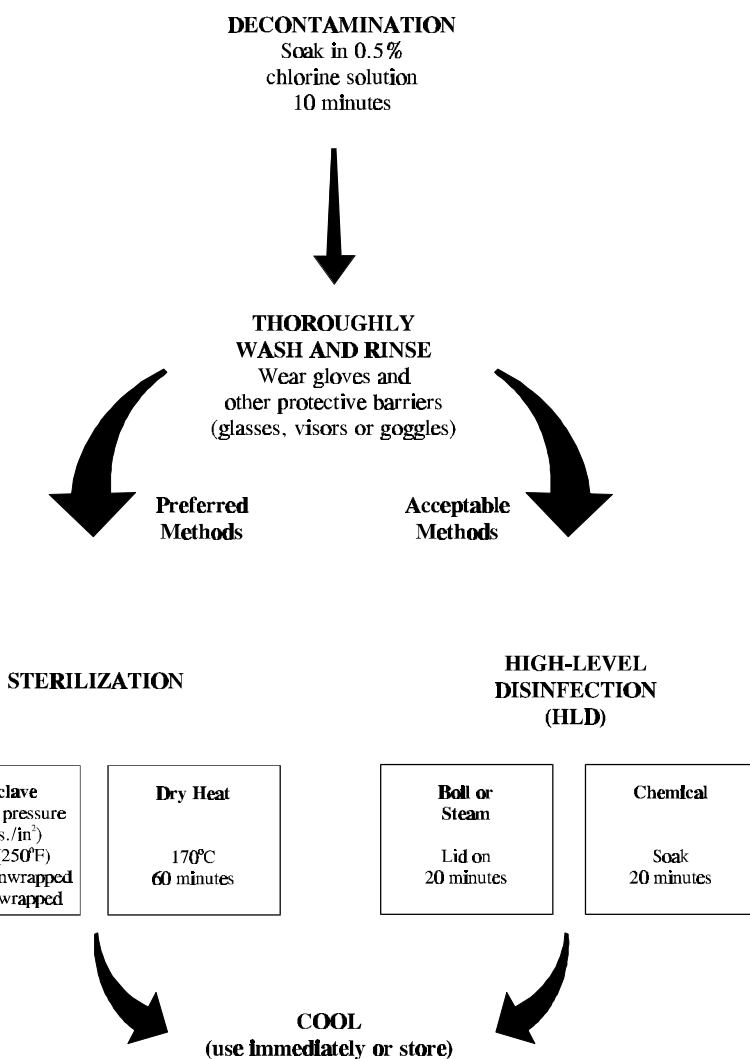
- Isolate patients only if secretions (airborne) or excretions (urine or feces) cannot be contained.

Finally, process instruments and other items (decontaminate, clean and high-level disinfect or sterilize) using recommended IP practices.

While primarily intended for use in countries with limited resources, the scientific data presented in this

manual are universally applicable. For example, the recommended IP practices and processes which are outlined in **Figure 1** are designed to minimize costs and the need for expensive, often fragile equipment, while at the same time assuring a high degree of safety. Moreover, data supporting their use, relative importance and applicability in situations where resources and manpower are limited are provided.

Figure 1—Key Steps in Processing Contaminated Instruments and Other Items



Recognition and Endorsement Process

As mentioned previously, it was recognized that unless the IP manual was universally accepted, little progress could be anticipated in improving IP practices in many countries. Therefore, the decision was made to seek international recognition and endorsement prior to publishing the manual. The International Infection Prevention Review (IIPR) Task Force was especially important to this process. (See **Appendix 1** for a list of members.) At a 2-day IIPR Task Force meeting held in June 1991, representatives from 12 international agencies, including WHO:

- critically reviewed the draft IP manual,
- resolved many of the technical discrepancies among existing materials, and
- assessed the appropriateness of the IP manual to serve as an international reference standard.

At this meeting the manual was endorsed by the IIPR Task Force members. Subsequently, it was endorsed by the International Planned Parenthood Federation (IPPF), IPAS and several USAID cooperating agencies and contractors.

The process of seeking consensus and endorsement provided the necessary credibility for what, at that time, was seen as a radical departure from the traditional role of infection control (i.e., prevention of serious disease transmission—not just attempting to minimize postoperative and hospital-acquired infections—should be a major component of the IP program).

Other factors which have contributed to acceptance of the infection prevention philosophy include the following:

- Initial and continued adherence to the doctrine that to be useful, the recommended IP practices must be easy-to-use, inexpensive and, most importantly, reflect the needs identified in the field.
- Belief of JHPIEGO staff and IP consultants that infection prevention should be an integral component of clinical contraceptive services, **not** a separate activity, as well as their willingness to “walk the talk.” Examples of this include:
 - IP training directed to all types of health professionals, not just nurses and OR technicians; and
 - incorporation of recommended IP practices as essential steps in providing a surgical contraceptive method and **not** as options for the clinician (e.g., the IP practices are included in JHPIEGO training materials as key steps in the learning guides and checklists as well as in training slide sets, photosets and videotapes).

The novel three-part design and layout of the manual also has been an important factor in this process. With publication of JHPIEGO's *Infection Prevention for Family Planning Service Programs* in 1992, practitioners had for the first time a single, inexpensive (US \$6) volume containing all the essential information needed by service providers to:

- Understand the fundamentals of infection prevention (scientific information section).
- Incorporate practical and simple recommended IP practices into all surgical contraceptive methods (generic guidelines section).

- Learn the key steps in setting up and performing essential IP practices (e.g., decontamination, waste disposal) and processes (“how-to” section).

Acceptance as an International Reference Standard

During the nearly 4 years since publication of the IP manual, the rationale for focusing on the two-fold IP strategy and the usefulness of the three-part design have been confirmed repeatedly. Not only has the manual enabled safer provision of surgical contraceptive methods for clients, but it has served to reassure health care providers and staff that use of simple interventions, such as handwashing and decontamination of instruments with dilute bleach (chlorine solution), makes performing surgery safer for them. Additionally, it has led to the acceptance of the manual as an international IP reference standard. Evidence to support this includes:

- Citation of the recommended IP practices in numerous published articles.
- Recognition by the United States Agency for International Development (USAID) (Technical Guidance Working Group, Volume 1, November 1994).
- Endorsement of the soon-to-be-published second edition by WHO, IPPE, the Pan American Health Organization (PAHO/WHO) and many USAID cooperating agencies (CAs) and contractors.

Initially printed in English, JHPIEGO has subsequently translated the manual into French, Portuguese, Russian and Spanish. To date, almost 27,000 copies have been used in JHPIEGO-sponsored activities and by other organizations (CAs, contractors and WHO). In

addition, all or parts of the manual have been translated by a number of other organizations for specific uses. For example, in 1993 PAHO/WHO adapted the IP manual and distributed Spanish versions to 10,000 hospitals in Latin America. WHO has prepared translations in Arabic and Vietnamese and the Government of Indonesia has published an edition in the Indonesian language.

A second edition of the IP reference manual currently is undergoing final review. Earlier drafts were field-tested in Nepal and Kenya and more recent drafts have been extensively reviewed by selected members of the IIRP Task Force and the 35 participants of IP Specialists Workshops held at JHPIEGO in September 1994 and 1995. At present, it is planned that the revision will be ready for publication in English in late 1996 with other language versions to follow.

Since 1992, JHPIEGO has developed, field-tested and produced a comprehensive package of infection prevention reference and training materials. These materials have allowed for the incorporation of IP as an integral part of all JHPIEGO programs.

Related Achievements

Highlights of key IP changes introduced during the past 4 years include the following:

- **Provision of IUD services was made more widely available and less expensive globally.**

By emphasizing the importance of loading the Copper T 380A IUD in the sterile package and using the no-touch insertion technique, the need for expensive sterile surgical gloves has been eliminated.

- **An IP system for Norplant® implants has been used to train the majority of Norplant implants trainers.**

Since 1991, practitioners from 13 countries, including the United Kingdom, have been qualified as Norplant implants trainers through JHPIEGO's project in Indonesia. A key component of the competency-based training approach used has been the IP system which makes insertion and removal of implants safer and less expensive (gloves and hypodermic syringes can be safely reused) and eliminates the need for an assistant to help with the procedure.

- **A three-phase approach for the safer disposal or reuse of syringes (and needles) in injectable contraceptive service provision was developed.**

The safe disposal of the syringes and needles used for injecting DMPA or NET-EN is a significant problem in many countries—both as a biohazard and environmental issue. With training, clinic staff can now learn how plastic (disposable) syringes can be easily and safely decontaminated and reused.

- **The effectiveness of steaming for the high-level disinfection (HLD) of surgical gloves was verified.**

In many countries, equipment for sterilization often is not available in FP/MCH clinics. Although HLD by boiling or soaking in chemical disinfectants is possible, neither is practical for processing surgical gloves which must be dried before use. In 1994 a series of experiments was conducted evaluating an alternate method, using an inexpensive (US \$3.50), commercially available steamer (rice cooker). The steamer consisted of a bottom pan for boiling water and

up to three steam pans stacked on top of each other and a lid to seal the assembly. Each pan had multiple holes in its bottom to permit the passage of steam upwards and condensed water back down. Based on temperature studies using an iron/Constantan thermocouple and bacteriologic studies using a standardized mixture of bacteria, fungi and heat-sensitive and heat-resistant endospores, steaming was found to be a practical, effective method for HLD of surgical gloves.

- **A practical IP system was developed to allow clinics without access to sterilization equipment to safely provide manual vacuum aspiration (MVA) services for the treatment of incomplete abortion.**

This IP system has been field-tested in Nepal. It incorporates use of steaming for the HLD of instruments, gloves and plastic items (e.g., MVA cannula and hypodermic syringes) that cannot be sterilized by autoclaving (high-pressure steam heat) or in a dry heat oven. It also introduces safer practices for the handling and disposal of contaminated waste materials.

Finally, progress in introducing the IP program globally has been tracked through JHPIEGO's automated program monitoring system (APMS), which breaks down the data into the following categories:

- Capability and capacity building
- Materials development and production
- Research and publications

Capability and Capacity Building

Since 1992, recommended IP practices have been introduced at some level of the primary health care system in 34 countries globally (**Table 1**).

Additionally, 5 countries (Egypt, Indonesia, Kenya, Nepal and Thailand) now have the capacity to conduct basic IP training. By the end of FY 96 at least 7 more countries (Bolivia, Mali, Peru, Senegal, Turkey, Uganda and Zimbabwe) will be able to integrate basic IP training into their reproductive health training courses. Nearly 20 countries will have incorporated

the recommended IP practices into their national reproductive health policy and service delivery guidelines.

During the last 18 months, 35 international advanced clinical trainers (physicians, nurses and midwives) and nine JHPIEGO staff/consultant trainers have been qualified as IP specialists. At present, through the efforts of these newly qualified IP trainers, infection prevention practices are being expanded rapidly in most of the major USAID-supported country programs.

Table 1—Countries with Infection Prevention Practices Incorporated into One or More Clinical Procedures

GLOBAL REGION	COUNTRY
Latin America/Caribbean	Bolivia, Brazil, Guatemala, Peru
Europe	United Kingdom
Africa	
Near East/North Africa	Egypt, Morocco, Tunisia, Turkey
West Africa	Cameroon, Ghana, Guinea, Mali, Senegal
East/Southern Africa	Burundi, Kenya, Rwanda, Tanzania, Uganda, Zimbabwe
Asia	
East Central Asia	Kazakhstan, Kyrgyz Republic, Russia, Tajikistan, Turkmenistan, Ukraine, Uzbekistan
South Asia	Bangladesh, India, Nepal, Thailand
Southeast Asia	Indonesia, Papua New Guinea, Philippines

Table 2—Infection Prevention Report Card

- 34 countries where IP practices have been initiated
- 5 countries providing basic IP training with 7 more to follow in FY 96
- 35 qualified international IP specialist trainers
- Nearly 20 countries with recommended IP practices built into national reproductive health policy

Research and Publications

In 1989, the first article briefly describing a set of IP practices that had the potential to become universally accepted was published by Tietjen and McIntosh. Subsequently, between 1990 and 1995, presentations on selected IP topics were given at meetings of the American Public Health Association, the Society for the Advancement of Contraception, the VIIIth World Congress on Human Reproduction, and the Asian and Oceanic Federation of Obstetrics and Gynecology. (Full citations for these presentations are provided in the reference list.) In 1993, “Infection Prevention Practices: Minilaparotomy and Laparoscopy” (Tietjen), was published as a chapter in the *Proceedings from the VIIIth World Congress on Human Reproduction and Joint IVth World Congress on the Fallopian Tube in Health and Disease*.

As described above, a small research project to evaluate the effectiveness of a steamer (rice cooker) to high-level disinfect surgical gloves was conducted in 1994. The results were reported at the *122nd Annual APHA Meeting* (McIntosh et al 1994), and the subsequent paper has been submitted for publication

to the *International Journal of Gynecology and Obstetrics*.

Goal and Objectives of the Infection Prevention Program

The **goal** of the JHPIEGO IP program during the next 2 years will be to continue to expand the availability of practical, inexpensive IP practices to reproductive health programs globally, especially those providing clinical family planning services.

Specific objectives will include the following:

1. To accelerate the transition from consultant-supported training, especially for basic IP training of health professionals, to training by international, regional or local (host-country) clinical and advanced trainers with IP qualifications.
2. To develop regional capability to provide advanced IP training to clinical trainers in the Latin America and possibly South Asia regions. (The content would approximate that provided in the IP specialist training course given in Baltimore.)
3. To improve the monitoring of IP practices in the countries in which JHPIEGO is working.
4. To distribute new IP research, especially appropriate international findings, as well as practical solutions to generic problems encountered in the field through JHPIEGO’s **ReproLineSM** Internet (WWW) service.
5. To conduct a biomedical research project evaluating the effectiveness of dry (gaseous) formaldehyde for sterilizing and high-level disinfecting laparoscopes and ancillary equipment (see **Appendix 2** for details).

6. To foster participation of international public health and medical leaders trained in infection prevention on key international medical and health care advisory committees and task forces.

Summary

Since its inception, JHPIEGO's infection prevention program has been extremely successful, having become a priority issue for USAID's Maximizing Access and Quality (MAQ) Task Force as well as part of USAID's strategy to improve the quality of family planning care. In addition, the IP manual, *Infection Prevention for Family Planning Service Programs*, is now an accepted international reference standard. The second edition of the manual, which will be published in 1996, has been prepared with assistance from several international and US-based organizations.

As detailed in this paper, the major impact of the IP program to date has been to introduce changes that make provision of surgical contraceptive methods and other invasive procedures safer for clients, service providers and support staff. This has been accomplished by systematically analyzing the problems observed in the field and then seeking appropriate solutions that are simple, scientifically sound and practical. With continued support, the efforts of newly qualified trainers and health professionals with IP skills will enable the recommended IP practices to be introduced in nearly all major USAID-funded countries in the next few years.

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Appendix 1

Members: International Infection Prevention Review Task Force (June 1991)

Elaine Larson, Chairperson

Professor and Nutting Chair in Clinical Nursing
The Johns Hopkins University
School of Nursing
Baltimore, Maryland

Tahar Alaoui

Professor of Obstetrics and Gynecology
Dean, University of Mohamed V
Rabat, Morocco

Marcia Angle, Clinical Officer

Program for International Training in Health (INTRAH)
Chapel Hill, North Carolina

Marcus Arvealo

Program Coordination Branch
International Planned Parenthood Federation/
Western Hemisphere Region
New York, New York

Allen Brimmer

Information and Training Division
USAID, Office of Population
Washington, DC

Cynthia Calla

Family Planning Services Division
USAID, Office of Population
Washington, DC

Betty Gonzales

Deputy Director, Medical Division
Association for Voluntary Surgical Contraception
New York, New York

Carlos Huezo

Medical Director
International Planned Parenthood Federation
London, England

Ethel Kagan

Infection Prevention Specialist
Vile St. Laurent, Quebec

Mohamed Kamel

Regional Director, Near East/North Africa
Pathfinder International
Watertown, Massachusetts

Jozef Kierski

Medical Officer
Division of Family Health/MCH
World Health Organization
Geneva, Switzerland

Anthony Klouda

Coordinator
AIDS Prevention Unit
International Planned Parenthood Federation
London, England

Ann Leonard

Deputy Director
IPAS
Carrboro, North Carolina

Kobchitt Limpaphayom

Associate Professor
Department of Obstetrics and Gynecology
Chulalongkorn University
Bangkok, Thailand

Mark Robbins

Medical Advisor
Family Planning Service Expansion and Technical
Support (SEATS)
Boston, Massachusetts

Appendix 2

Sterilization and High-Level Disinfection of Laparoscopic Equipment Using Formaldehyde Gas

In the early 1970s, JHPIEGO pioneered the introduction and successful use of laparoscopy as a surgical method for voluntary female sterilization in developing countries. Today, in more than 100 developing countries, laparoscopic tubal occlusion, using either Yoon Falope rings or the Filshie clip, accounts for more than a million sterilizations per year.

A continuing problem with the use of laparoscopy in countries where resources are limited is the lack of practical, inexpensive methods of high-level disinfecting the laparoscopes between cases and sterilizing them at the end of the day. Conventional sterilization processes, such as autoclaving (steam) or dry heat, cannot be used because they would damage the optical components. This problem has been solved in some countries by using aqueous glutaraldehydes (e.g., Cidex[®]), which are excellent chemical high-level disinfectants, between cases and employing gaseous ethylene oxide for sterilization. In many countries, however, ethylene oxide and the systems for safely using this highly toxic chemical are not available; and glutaraldehydes, which cost approximately US \$20 dollars per gallon and must be replaced frequently, are too expensive. An added disadvantage of glutaraldehydes is that because they are manufactured in only a few countries, they must be imported.

To circumvent this problem, many countries continue to use liquid formalin. Although inexpensive and readily available worldwide, formalin releases a wet vapor containing formaldehyde gas, which is highly irritating to mucous membranes. Formaldehyde also is mutagenic and carcinogenic in animals and is classified

by the Environmental Protection Agency as a potential human carcinogen. As a consequence, in the early 1980s the Occupational Safety and Health Administration set the permissible exposure limit (PEL) at 3ppm as an 8-hour time-weighted average (TWA). In 1987 this was reduced to 1ppm.

Although an excellent chemical sterilant, because of its respiratory (nasal) and eye irritation even at low levels, formalin has not been used in the US or other developed countries since the 1940s to sterilize or high-level disinfect surgical instruments, rubber goods or other inanimate items. Unfortunately, in developing countries, formalin still is widely used not only for disinfecting instruments but also for fumigation of contaminated operating rooms—a practice which was shown to be ineffective many years ago. With both of these processes, staff at all levels often are exposed to concentrations of formaldehyde gas greatly exceeding the PEL.

For the past 2 years at JHPIEGO we have been studying the problem of how to safely (and inexpensively) sterilize and high-level disinfect laparoscopes. A potential solution which we feel should be investigated involves the novel use of dry formaldehyde gas under controlled release conditions. This patented process called ALDISTER[®] was developed by researchers at Becton Dickinson Research Center for National Air and Space Administration (Tulis 1972). It is a self-sterilizing process in which the active sterilant (monomeric formaldehyde gas) is liberated at a controlled rate from paraformaldehyde crystals following exposure to low temperatures (i.e., from

30–50°C) into a closed container, in this case a plastic bag. The initial concentration of molecular formaldehyde within a zip-locked bag containing a surgical instrument is sufficient to sterilize it within 60 to 120 minutes, after which the formaldehyde molecules slowly diffuse through the plastic bag, at a rate dependent on the bag's composition and thickness, into the atmosphere. At no time does the concentration in the room exceed the PEL. An added advantage is that when the process is completed, no residual formaldehyde molecules remain on the now sterile instrument. Thus, the need for rinsing the instrument with sterile water before use is eliminated. Because the ALDESTERI process has been used successfully to sterilize diverse medical, surgical and laboratory devices and instruments, we believe it could be a cost-effective method for sterilizing or high-level disinfecting laparoscopes and other heat sensitive surgical items.

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